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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/557,536	01/12/2007	David Strand	005092.00078	8811
22910 BANNER & W	7590 05/07/201 <sup>.</sup> ITCOFF, LTD.	0	EXAMINER	
28 STATE STREET			SCHNEIDER, CRAIG M	
SUITE 1800 BOSTON, MA 02109-1701			ART UNIT	PAPER NUMBER
			3753	
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# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		Application No.	Applicant(s)			
Office Action Summary		10/557,536	STRAND ET AL.			
		Examiner	Art Unit			
		CRAIG M. SCHNEIDER	3753			
Period fo	The MAILING DATE of this communication app or Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)☑	Personsive to communication(s) filed on 3/1/1/	0 and the supplemental on 1/20/2	10			
·	Responsive to communication(s) filed on <u>3/1/10 and the supplemental on 4/29/10</u> .  This action is <b>FINAL</b> .  2b) This action is non-final.					
<i>'</i> —	, <del></del>					
ا ال	21					
	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Dispositi	on of Claims					
4)🖂	Claim(s) <u>1-5,7-10,12,13,15-17,19,21-24 and 26</u>	$\underline{0}$ is/are pending in the application				
	4a) Of the above claim(s) is/are withdrawn from consideration.					
	5) Claim(s) is/are allowed.					
	6)⊠ Claim(s) <u>1-5,7-10,12,13,15-17,19,21-24 and 26</u> is/are rejected.					
· ·	Claim(s) is/are objected to.	<u>,</u> 10/410 10/00100.				
·	· · · ——	coloction requirement				
8)	Claim(s) are subject to restriction and/or	election requirement.				
Applicati	on Papers					
9)□	The specification is objected to by the Examine	r.				
10)⊠ The drawing(s) filed on <u>3/1/10</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.						
,						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority u	ınder 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
2)  Notic 3) Inforr	t(s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date	4)  Interview Summary Paper No(s)/Mail Da 5)  Notice of Informal P 6)  Other:	te			

Art Unit: 3753

#### **DETAILED ACTION**

## **Drawings**

1. The drawings were received on 3/1/10. These drawings are acceptable.

# Claim Rejections - 35 USC § 102

- 2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 3. Claims 1, 3-5, 7-10, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Ivory et al. (6,277,258).

Ivory et al. disclose a bulk fluid flow gate (100) comprising a first fluid flow chamber (112), and at least one electrode (22) operative when energized to generate an electric field in the first fluid flow chamber, wherein the first fluid flow chamber comprises a first fluid inlet port (320) configured to receive bulk fluid flow into the first fluid flow chamber, a first fluid outlet port (114) configured to pass bulk fluid from the first chamber, a second fluid inlet port (318) configured to receive sample fluid flow into the first fluid flow chamber at a location between the first fluid inlet port and the first fluid outlet port, and a second fluid outlet port (116) configured to pass fluid from the first fluid flow chamber, the first fluid outlet port and the second fluid outlet port being on opposite sides of the first fluid inlet port, and the bulk fluid flow gate when receiving a bulk fluid flow into the first fluid flow chamber via the first fluid inlet port, presenting greater hydrodynamic resistance to passing fluid from the first fluid flow chamber via the second outlet port than via the first fluid outlet port (col. 7, line 26 to col. 9, line 24).

Page 3

Note: The device as disclosed by Ivory et al. is capable of performing the functional language as claimed with the structure as disclosed and with the intended fluid. The inlet and outlet ports as labeled per the reference are merely labels of their intended use. The Ivory et al. reference is capable of having the ports as indicated above connected as inlet and outlet ports and therefore would be capable of performing the intended use recitations of the claims. Further, the material that is worked upon by the device does not limit an apparatus claim if the apparatus is capable of working on the material (see MPEP 2115).

Regarding claim 3, the second fluid inlet port is configured to receive fluid flow into the first fluid flow chamber at a flow rate lower than the first fluid inlet port. The device of Ivory et al. is capable of having the fluid entering the second fluid inlet port at a flow rate lower than the first fluid inlet port.

Regarding claim 4, the at least one pair of electrodes is positioned proximate the first fluid flow chamber, being operative when energized to generate an electric filed operative in the first fluid flow channel to move charged analyte received into the first fluid flow chamber via the second inlet port toward the second outlet port through a fluid flowing from the first inlet port to the first outlet port. The device of Ivory et al. is capable of performing the functional language.

Regarding claim 8, the first entry port is positioned at an obtuse angle to the axial direction of the first chamber. The axial direction of the first chamber has not been defined per the claims; therefore the examiner is utilizing an axis through the first chamber that creates and obtuse angle with the first entry port.

Art Unit: 3753

Regarding claim 9, the first chamber further comprises separation media (16) selected from the group consisting of molecular sieves, ion-exchange media, and size exclusion media (col. 6, lines 18-44).

# Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. Claims 2 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over lvory et al. (6,277,258).

lvory et al. disclose all the features of the claimed invention except that the gate has a microscale chamber.

It would have been an obvious matter of design choice to make the gate of Ivory et al. microscale, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

Regarding claim 12, Ivory et al. disclose all the features of the claimed invention except that the first and second exit ports are positioned parallel to the axial direction of the first chamber.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the first and second exit ports arranged in a parallel fashion

Art Unit: 3753

to the axial direction of the first chamber, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japiske, 86 USPQ 70.

6. Claims 15-17, 19, 21-24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ivory et al. (6,277,258).

lvory et al. discloses a bulk fluid flow gate (100) comprising a at least one electrode (22) for generating an electric field, a first chamber (112) in communication with the at least one electrode, the first chamber comprising a first entry port (320), a first exit port (114), a second entry port (318) positioned between the first entry port and the first exit port, and a second exit port (116)(col. 7, line 26 to col. 9, line 24). Ivory et al further disclose that the bulk fluid flows in a counterflow direction of the sample fluid (col. 11, lines 43-50). Ivory et al. fails to disclose that a sample comprising at least one charged analyte that further includes lipids, micelles, detergent or vesicles is introduced into the first chamber through the second entry port and that a bulk fluid flows substantially against the direction of migration of the at least one charged analyte in the electric field of the first chamber, the bulk fluid flowing with sufficient hydrodynamic force such that the hydrodynamic resistance at the first exit port is substantially greater than the hydrodynamic resistance at the second exit port.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize various types of fluids including a bulk fluid in the first entry port and a sample comprising at least one charged analyte in the second entry port of Ivory et al., since Ivory et al. disclose that the flow of "sample" flows in a

counterflow of the bulk fluid (buffer) and the arrangement as presented above would be one viable arrangement that would accomplish the effect of the sample and bulk fluids flowing in a counterflow orientation.

Regarding claims 16 and 17, the apparatus as disclosed with the fluids entering into the entry ports would allow the charged analytes to elute through the first or second exit port depending on the electric field.

Regarding claim 19, in which the sample is introduced into the first chamber using an injector (col. 9, lines 25-36). A centrifugal pump or syringe pump would be considered an injector.

Regarding claim 21, the bulk fluid flow gate comprises an electrode housing (120) containing the at least one electrode.

Regarding claim 22, flowing a coolant into the electrode housing via conduits 215 and 217.

Regarding claim 23, the force of the electric field is disclosed as being adjustable (abstract) therefore with the bulk fluid entering the first entry port and the sample entering the second entry port the electric field that would be generated would exceed the hydrodynamic force generated by the bulk fluid flow so that the analyte migrates towards the second exit port.

Regarding claim 24, the electrode would apply an electric field gradient to the first chamber.

Art Unit: 3753

### Response to Arguments

- 7. Applicant's arguments filed 3/1/10 have been fully considered but they are not persuasive. The applicant is arguing that the Ivory et al. does not anticipate the claim language. The applicant has indicated that Ivory et al. does not indicate at least one electrode and a first fluid flow chamber having a first fluid inlet port, a first fluid outlet port, a second fluid inlet port at a location between the first fluid inlet port and the first fluid outlet port, and a second fluid outlet port, the first fluid outlet port and the second fluid outlet port being on opposite sides of the first fluid inlet port. The applicant further indicates that the relationship as claimed between the locations of the inlet ports and the outlet ports is not met by the Ivory et al. reference. The structural limitations as stated in the above arguments were addressed in the office action dated 9/1/09 and have been restated again above.
- 8. In response to applicant's argument that the intended use of the various ports is not being met, i.e. inlet and outlet ports and their locations with respect to each other; a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

#### Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3753

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRAIG M. SCHNEIDER whose telephone number is (571)272-3607. The examiner can normally be reached on M-F 8:00 -4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robin Evans can be reached on (571) 272-4777. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3753

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. M. S./ Examiner, Art Unit 3753 May 5, 2010 /John Rivell/ Primary Examiner, Art Unit 3753